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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,257	04/23/2001	Robert A. Scott	6512-11EJF	7160

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EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,257

Applicant(s)

SCOTT ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The objections to and 35 U.S.C. rejections of claims 1-30 in Paper # 5 (08/28/02) have been withdrawn due to Applicant's cancellation of said claims in Paper # 7 (filed 03/11/02).

New Rejections

Claim Rejections - 35 USC § 112

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 31-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In independent claims 31 and 56:
- a. It is unclear what the container is without a description of the structure.
 - b. It is unclear what the term "deliverable" means. Any material is deliverable as in transportable.
 - c. It is unclear what is meant by the limitation of "gelatin as the principal container forming material". Does it mean that the amount of gelatin relative to the other film-forming components is minor?
4. Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what a "setting system" is.

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5. Claims 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what a "sequestering agent" is.

6. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the amount of water in the container composition is the residual water content which has been stabilized.

7. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what an exocellular polysaccharide.

Claim Rejections - 35 USC § 103

8. Claims 31-33, 36-38, 44-48, 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan (US 5,885,617).

Jordan teaches a moisture barrier film coating which uses a liquid coating solution which comprises polyvinyl alcohol (PVA), plasticizer (soya lecithin), coloring agent (colorant) of iron oxide, titanium oxide or natural colors and exocellular polysaccharides which are a subset of hydrolloids, such as alginates and natural gums (plasticizer) (column 2, lines 15-65). The amount of PVA is 30 to 99 %, coloring agent 0 to 60 %, plasticizer 0.2 to 10 %, 0 to 2 % of alginates (hydrocolloid suspending agent) (column 3, lines 1-10). Tartrazine aluminum contains aluminum cations which would comprise less than 5% (less than a third of the 14 weight % of

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the salt component (column 5, lines 50-60). Xanthan (gum) (exocellular polysaccharide) is present in one of the examples (column 3, lines 30).

Jordan teaches that the liquid solution is sprayed onto the pharmaceutical tablets, effectively encapsulating and thus containing each tablet (column 3, lines 50-60), thereby effectively forming an encapsulator container. It would have been an obvious variation in the art to dipcoat the tablets instead.

With respect to the container comprising two halves sealed together, and that the two halves are sealed by a liquid fusion process, even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The final product is still a whole container.

9. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan as applied to claims 31-33, 36-38, 44-48, 50-56 above, and further in view of Rhodes et al. (GB 2 006011).

Jordan teaches an encapsulating container, but fails to teach a coating ontop of the encapsulator.

Rhodes et al. teaches that cellulose acetate phthalate is a suitable enteric coating for a capsule wherein the enteric coating is relatively insoluble in the acid medium of the stomach, but disintegrates in the medium of the small intestine (column 3, lines 20-35).

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Because Rhodes et al. teaches that cellulose acetate phthalate is a suitable enteric coating for a capsule, it would have been obvious to one of ordinary skill in the art to have used the coating on top of the capsule of Jordan in order to obtain a capsule suitable for enteric delivery.

10. Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan as applied to claims 31-33, 36-38, 44-48, 50-56 above, and further in view of Gilbert et al. (US 4,349,563).

Jordan teaches an encapsulating film coating solution comprising PVA, hydrocolloids and metal cations, but fails to specifically teach the presence of a sequestering agent.

Gilbert et al. has pharmaceutical compositions (title) of PVA compositions which contain trisodium citrate (column 9, lines 9-18 and column 10, lines 29-36) designated as one of the sequestering agents in a list, in the amount of 0.001 to 2 % by weight of the composition. Gilbert et al. teaches that the sequestering agent prevents the precipitation of insoluble salts of the metal cations (column 2, lines 45-68).

Because Gilbert et al. teaches that the sequestering agent prevents the precipitation of insoluble salts of the metal ions, it would have been obvious to one of ordinary skill in the art to have used the sequestering agent of Gilbert et al. in the metal cation containing coating solution in the invention of Jordan in order to obtain an encapsulating solution which suppresses precipitation of the insoluble salts of the metal cations.

11. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan as applied to claims 31-33, 36-38, 44-48, 50-56 above, and further in view of Yamamoto et al. (US 5,264,223).

Jordan teaches the capsule containing alginate but not carrageenan which is also derived

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from seaweed, and fails to teach the concerted amounts of hydrocolloid setting agent, cations, and water present in the encapsulating coating.

Yamamoto et al. has a capsule for pharmaceutical use (title). The capsule comprises a water-soluble cellulose derivative and a setting (gelatinizing) agent (abstract). The setting agents disclosed are polysaccharides such as carrageenan and the cations listed (column 3, 1-20). Other hydrocolloids taught are polysaccharides of tamarind seed (tamarind gum) and curdlan (column 3, lines 1-4). Yamamoto et al. teaches that the amount of film forming polymer is 92 to 94 %, the amount of setting (gelatinizing) agent is 0.1 to 0.5 % by weight, the amount of cation (auxilliary) is 0.01 to 0.5 % by weight and the amount of water is 4 to 6 % by weight of the capsule film (column 4, lines 25-40) in order to obtain a good hard capsule film via dip molding (conventional immersion molding method) (column 3, lines 40-68).

Because Yamamoto et al. teaches that the concerted amounts of the film forming polymer, the setting agent, the cations and water are needed in order to obtain a good hard capsule film via dip molding, it would have been obvious to one of ordinary skill in the art to have used the amounts taught by Yamamoto et al. for the setting agent, cations and water in the invention of Jordan in order to obtain a good hard film encapsulator via dip molding.

12. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan as applied to claims 31-33, 36-38, 44-48, 50-56 above, and further in view of Frensch et al. (US 4,244,836).

Jordan teaches the polyvinyl alcohol film coating encapsulating container, but fails to teach the addition of an antifoaming agent.

Frensch et al. teaches microcapsules having a container (shell) consisting of water-soluble polyvinyl alcohol (PVA) encapsulating pharmaceuticals (column 2, lines 25-60). A

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suitable antifoaming agent is added during mixing of the components of the encapsulating dispersion to suppress disturbing foam formation (column 4, lines 1-15).

Because Frensch et al. teaches that foam formation is disturbing, it would have been obvious to one of ordinary skill in the art to have used the antifoaming agent of Frensch et al. in the coating dispersion of Jordan in order to obtain a capsule with the desired homogeneity.

Response to Arguments

13. Applicant's arguments with respect to the art rejections of claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

8H
05/30/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/3/02